**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW MEXICO**

PRISCILLA GARCIA,

Plaintiff,

v. No. 1:21-cv-00666 MIS/JFR

BAYER ESSURE, INC., et al.,

Defendants.

**MEMORANDUM OPINION AND ORDER GRANTING**
**DEFENDANTS' MOTION TO DISMISS THE FIRST AMENDED COMPLAINT**

THIS MATTER comes before the Court on Defendants' Motion to Dismiss the First Amended Complaint. ECF No. 23. Plaintiff responded, and Defendants replied. ECF Nos. 27, 28. Having considered the parties' submissions, the record, and the relevant law, the Court will **GRANT** the Motion.

## BACKGROUND

Plaintiff's claims arise out of injuries she allegedly suffered as a result of being implanted with the Essure permanent contraception device ("Essure device"). *See* ECF No. 22 at 1. The Essure device consists of a coil that is implanted into each fallopian tube, which causes the body to form a scar tissue barrier to block fertilization. *Id.* at 33. The Food and Drug Administration ("FDA") regulates the Essure device as a Class III medical device, meaning it was required to pass a special approval process before reaching the market. ECF Nos. 23 at 2; 22 at 8. It did so in 2002, and this approval has never been withdrawn. *See* ECF Nos. 22 at 9; 23-1 at 2; 23-4 at 2. However, Defendants discontinued sales of the Essure device after December 31, 2018. *See* ECF No. 23 at 4; 23-9 at 2. Known side effects of Essure include bloating, pain, abnormal bleeding, and other symptoms. *See* ECF Nos. 5-7 at 4; 22 at 33, 45.

Plaintiff was implanted with the Essure device in October of 2011 and had removal surgery in November of 2018, whereupon she alleges she discovered she had medical problems resulting from the device. ECF No. 22 at 41. Plaintiff claims that as a result of her implantation with the Essure device, she experienced "severe but intermittent abdominal/pelvic pain" that was "so debilitating that it would intermittently hinder her ability to walk for long distances, stand up, sit down and get out of bed." *Id.* She also alleges she experienced "spotting and bleeding in between her menstruation periods, hair loss, and a metal taste in her mouth," and that these symptoms required additional surgery to remove the Essure device. *Id.* at 41–42.

Plaintiff filed her original Complaint in state court on February 25, 2021, alleging negligence, fraud, claims under strict products liability, and other claims pursuant to New Mexico state law related to her injuries. ECF No. 1-1 at 45–72. Defendants removed the case to this Court on July 20, 2021. ECF No. 1 at 1.

Defendants moved for dismissal of Plaintiff's claims against them on the basis that Plaintiff's claims were, in their entirety, preempted by federal law and are otherwise inadequately pled as required by Federal Rule of Civil Procedure ("Rule") 12(b)(6). ECF No. 5 at 1. On September 28, 2022, the Court dismissed Plaintiff's claims without prejudice and allowed amendment within thirty days. ECF No. 21 at 18–19.

Plaintiff has since filed her Amended Complaint, which includes a new claim for negligence per se, more information on her medical symptoms, and other more minor changes. *See generally* ECF No. 22. Defendants now move for dismissal of the Amended Complaint on similar grounds as their earlier motion. *Compare* ECF No. 5 *with* ECF No. 23.

## LEGAL STANDARD

In 1976, Congress passed the Medical Device Amendments ("MDA"), 21 U.S.C. § 360c *et seq*., to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., thereby imposing a detailed federal oversight regime for medical devices, including various levels of oversight depending on the risk level of a given device. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Under the MDA, Class I devices are subject to the lowest level of oversight, and Class III devices are subject to the highest. *Id.* at 316–17; *see* 21 U.S.C. § 360c(a)(1)(A), (C). The MDA also established a rigorous premarket approval ("PMA") process for Class III devices, which entails an average of 1,200 hours on the part of the FDA to review each application. *Riegel*, 552 U.S. at 318. The process requires that the FDA find "reasonable assurance" of a given Class III device's "safety and effectiveness," § 360e(d), but allows the FDA to nonetheless "approve devices that present great risks if they [] offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318. The PMA process includes review of a device's proposed labeling and may be conditional on adherence to certain performance standards or other restrictions. *Id.* at 318–19. After PMA, Class III devices are subject to reporting requirements, and the FDA has the power to withdraw approval based on new data. *Id.* at 319; § 360e(e)(1).

"Congress created no private cause of action in the MDA . . . ." *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1280 (10th Cir. 2021). Indeed, "the statute preempts *any* effort to use state law to impose a new requirement" on a device the FDA has already approved. *Caplinger v. Medtronic, Inc*., 784 F.3d 1335, 1344 (10th Cir. 2015). The MDA includes an express preemption provision, which states:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The MDA also states that—except for those actions brought by states themselves—all "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a), (b)(1).

The MDA does not always preempt state tort suits, but for a claim to survive, state law must impose "parallel" duties to those found in the federal regulations. *Caplinger*, 784 F.3d at 1338 (construing *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)). That is, to survive preemption, "a plaintiff must plead conduct that (1) violates the FDCA (because state law may not impose additional or different duties) and (2) would be actionable under state law independently of the FDCA (because a plaintiff may not seek to enforce the FDCA)." *Brooks*, 985 F.3d at 1279. Where a plaintiff fails to thread this needle, her claims are subject to dismissal. *Id.* The introduction of federal law into the realm of medical devices has thus left, "by both express and implied preemption, only a narrow gap within which a plaintiff can plead a tort claim arising from the failure of a medical device." *Id.* at 1276.

As to pleading, pursuant to Rule 12(b)(6), a party may move for dismissal if the complaint fails "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To survive a Rule 12(b)(6) motion, the complaint "must contain sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'"[1] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This pleading standard does not

[1] As Defendants note, ECF No. 28 at 2–3, Plaintiff's reliance on *Conley v. Gibson*, 355 U.S. 41 (1957) is misplaced, as the Supreme Court abrogated *Conley* in 2007. *Twombly*, 550 U.S. at 560–563.

impose a probability requirement, but it demands "more than a sheer possibility that a defendant has acted unlawfully." *Id*. Mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" will not suffice. *Twombly*, 550 U.S. at 555. Although the court must accept the truth of all properly alleged facts and draw all reasonable inferences in the plaintiff's favor, the plaintiff still "must nudge the claim across the line from conceivable or speculative to plausible." *Brooks*, 985 F.3d at 1281.

**DISCUSSION**

Defendants again argue that Plaintiff's six theories of liability alleged in her Amended Complaint—design defect, failure-to-warn, failure-to-report, misrepresentation, manufacturing defect, and failure-to-train—are all "expressly preempted by § 360k(a), impliedly preempted by § 337(a), or both." ECF No. 23 at 6. Defendants contend that "Plaintiff's minimal amendments fail to overcome preemption and do not otherwise make her claims plausibly pled." *Id.* at 2. Defendants also maintain the Court should dismiss Plaintiff's claims because she has still failed to plead facts showing their actions actually *caused* her injuries and because her misrepresentation claims are not pled with adequate particularity. *Id.* at 11. Defendants argue that Plaintiff "presents no factual allegations to articulate *how* any alleged negligence, breach of warranty, or any other tortious conduct caused her injuries." *Id*. Defendants, therefore, argue that her claims should be dismissed. *Id.*

Plaintiff, meanwhile, maintains that her claims are not preempted as she has adequately pled that Defendants violated New Mexico laws parallel to the federal regulations. ECF No. 27 at 2. Plaintiff also contends that the Court should excuse any defect in causal pleading as she "is not in possession of the imaging that would prove that her device either 1) migrated or was 2) misplaced . . . ." *Id.* at 8.

As a preliminary matter, the Court will address Plaintiff's argument that Defendants "settled most Essure lawsuits in August of 2020," including "thousands of Plaintiff[s] who brought meritorious claims." ECF No. 27 at 2. Aside from the fact that a court cannot decide a dispute which is not before it, or treat one plaintiff identically to another plaintiff who might be differently situated, the Court observes that August 2020 settlements predate the Tenth Circuit's 2021 decision in *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272 (10th Cir. 2021). The Court will therefore not consider this argument, and will proceed to analyze Plaintiff's own claims.

## I. Whether Plaintiff's Negligence Claims Parallel Federal Law

Plaintiff states her arguments regarding preemption very generally. ECF No. 27 at 5–7. She alleges, for example, that her "common law negligence claims are parallel to the federal regulations governing this specific Essure device," listing twenty-two separate regulations in a string citation. *Id.* at 7 (citing 21 C.F.R. §§ 803.10; 803.50; 803.52; 803.53; 803.56; 806; 814.1; 814.3; 814.9; 814.20; 814.37; 814.39; 814.80; 814.82; 814.84; 820.5; 820.20; 820.22; 820.25; 820.30; 820.70; 820.160); *see also* ECF No. 22 at 50–51. Defendants, meanwhile, maintain that "[n]one of that shows the Court how these *specific* negligence claims—asserting failure to warn, failure to report, design defect, negligent manufacturing, and negligent training—avoid preemption by paralleling federal requirements." ECF No. 28 at 5–6.

Despite this lack of explanation on the part of Plaintiff, the Court has examined the cited regulations, also known as Current Good Manufacturing Practices ("CGMPs"), which apply to FDA-approved medical devices in general. Section 803 involves reporting requirements to the FDA, as does Section 806. Section 814 generally describes procedures of premarket approval, as well as post-approval requirements. Section 820, meanwhile, generally describes quality system

regulation, including—among other things—quality auditing, design controls, production and process controls, and distribution.

CGMPs in general tend to be subject to interpretation, as they apply to all medical devices, and have therefore been found by various courts to be too unspecific to defeat preemption. *See, e.g.*, *Littlebear v. Advanced Bionics, LLC*, 896 F. Supp. 2d 1085, 1091 (N.D. Okla. 2012); *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009) (CGMPs are "inherently flexible" and are "simply too generic, standing alone, to serve as the basis for Plaintiff's manufacturing-defect claims"); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 278−79 (E.D.N.Y. 2009) ("CGMPs are intended to serve only as an umbrella quality system providing general objectives medical device manufacturers must seek to achieve.") (internal quotation marks omitted); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) ("Since these regulations are open to a particular manufacturer's interpretation, allowing them to serve as a basis for a claim would lead to differing safety requirements that might emanate from various lawsuits."). The Tenth Circuit generally prefers leaving such interpretation to the relevant regulatory agency. *See Cottrell, Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1255 (10th Cir. 1999) (quoting with approval the district court's assertion that "claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA").

It is true that at least one court has found that, while some CGMPs are too vague to be capable of enforcement, others may indeed "impose a concrete requirement on a manufacturer that embodies a standard of care related to the safety and effectiveness of the device," and thereby enable parallel state claims to avoid preemption. *Purchase v. Advanced Bionics*, LLC, 896 F. Supp. 2d 694, 698 (W.D. Tenn. 2011) (construing *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x

436, 440 (6th Cir. 2010)). Here, however, Plaintiff has not addressed this issue at all, failing to even explain to the Court how application of any particular CGMP prevents preemption of any specific state claim. *See Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 679 (10th Cir. 1998) ("Arguments inadequately briefed in the opening brief are waived . . . ."); *see also Olmstead v. Bayer Corp.*, No. 3:17-CV-387 FJS/DEP, 2017 WL 3498696, at *4 n.3 (N.D.N.Y. Aug. 15, 2017) (finding express preemption where "Plaintiff failed to make any attempt to connect [her] string of citations [to CGMPs] to the factual allegations in her complaint"). The Court therefore finds this argument unavailing.

**II. Design Defect Claims**

Next, Defendants argue that because Plaintiff does not allege that Defendants departed from the design the FDA approved, her design defect claims are expressly preempted. ECF No. 23 at 6–7. Defendants contend that Plaintiff's design defect allegations are unchanged from the original Complaint and preempted for the same reasons. *Id.* at 4. Plaintiff does not address these arguments in her Response, and any counterarguments are thus waived. *See generally* ECF No. 27. Plaintiff instead generally alleges that her claims are parallel state claims and are not preempted. *Id.* at 5–7.

For the same reasons stated in the Court's prior Order, these claims shall be dismissed. *See* ECF No. 21 at 6–7.

**III. Failure-to-Warn Claims**

Next, Defendants argue that Plaintiff's failure-to-warn claims are both expressly and impliedly preempted, because Plaintiff does not allege that Defendants deviated from the FDA-approved labeling. ECF No. 23 at 7. Defendants maintain that Plaintiff's amendments do not affect the preemption analysis. *Id.* Defendants also contend that New Mexico's learned intermediary

doctrine narrows the state cause of action in the medical context by requiring warnings only to physicians, and that she therefore has no parallel claim under state law. ECF No. 23 at 7–8.

Plaintiff does not address these arguments in her Response, and any counterarguments are therefore waived. *See generally* ECF No. 27. Plaintiff instead generally alleges that her claims are parallel state claims and are not preempted. *Id.* at 5–7.

In New Mexico, "where dangers from use [of a product] can be anticipated, the manufacturer must provide adequate warnings or the product is defective." *Serna v. Roche Labs*, 684 P.2d 1187, 1189 (N.M. Ct. App. 1984) (citing Restatement (Second) of Torts § 402A cmt. h)). However, "[w]here the product is a prescription drug, the manufacturer's duty to warn is fulfilled if it warns the physician, not the patient." *Id*. At least one court in this District has predicted that the Supreme Court of New Mexico would adopt the learned intermediary doctrine as applied to surgically implanted medical devices. *Nowell v. Medtronic Inc.*, 372 F. Supp. 3d 1166, 1255 (D.N.M. 2019), aff'd, No. 19-2073, 2021 WL 4979300 (10th Cir. Oct. 27, 2021). The Court concurs, and therefore finds that under New Mexico law, the Amended Complaint fails to state a claim as to failure-to-warn. To the extent that Plaintiff argues Defendants failed to "fully inform Plaintiff's healthcare providers regarding the proper implantation technique and necessity of follow[-]up imaging to determine correct positioning" of the device, Plaintiff fails to allege that her device was actually improperly implanted or positioned. ECF No. 22 at 42.

These claims shall thus be dismissed. *See* ECF No. 21 at 8–10.

**IV. Failure-to-Report Claims**

Defendants argue that Plaintiff's failure-to-report claims are both expressly and impliedly preempted, as they are merely improper attempts to privately enforce the MDA with no parallel state cause of action. ECF No. 23 at 7. Plaintiff does not address these arguments in her Response,

and any counterarguments are therefore waived. *See generally* ECF No. 27. Plaintiff instead generally alleges that her claims are parallel state claims and are not preempted. *Id.* at 5–7.

Plaintiff now alleges that Defendants should have reported its adverse events to "the medical community or patients," through "some other form of communication." ECF No. 22 at 46. Plaintiff further alleges that she "saw a brochure advertisement for the Essure® device in her provider's office . . . ." *Id.* at 41. Defendants argue that any claim based on failure to report adverse events to patients such as Plaintiff is preempted, as it would be "'different from, or in addition to' the requirements under federal law," which "requires that [Defendants] send adverse-event reports to [the] FDA and no one else." ECF No. 23 at 8.

Indeed, as stated in the Court's prior Order, the Tenth Circuit has squarely held that "only the federal government may enforce reporting requirements," and such claims are therefore impliedly preempted.[2] ECF No. 21 at 10 (quoting *Brooks*, 985 F.3d at 1281). As discussed in the Court's prior Order, these claims are therefore preempted and shall be dismissed. *See* ECF No. 21 at 10–11.

**V. Misrepresentation Claims**

Defendants argue that Plaintiff's misrepresentation claims are expressly preempted and that they are not pled with the particularity required by Rule 9(b). ECF No. 23 at 9, 16–17. Plaintiff does not address these arguments in her Response, and any counterarguments are therefore waived. *See generally* ECF No. 27. Plaintiff instead generally alleges that her claims are not preempted as they are parallel state claims and that her amended claims are adequately pled. *Id.* at 3–7.

[2] Plaintiff has not argued that the state law, including failure-to-warn tort law, parallels the federal reporting regulations. *See generally* ECF No. 27. In any event, such claims are foreclosed as discussed in the preceding section.

For the same reasons stated in the Court's prior Order, these claims are preempted and shall be dismissed. *See* ECF No. 21 at 10–11.

**VI. Manufacturing Defect Claim**

Defendants allege that Plaintiff's new claim of negligence per se is preempted, as such liability does not exist independently under state law. ECF No. 23 at 10. Defendants also argue that the manufacturing defect claims are expressly preempted and inadequately pled. *Id.* at 9–10. Plaintiff does not address these arguments in her Response, and any counterarguments are therefore waived. *See generally* ECF No. 27. Plaintiff instead generally alleges that her claims are not preempted as they are parallel state claims, and that her amended claims are adequately pled. *Id.* at 3–7.

As to the adequacy of the pleading, Plaintiff has added additional information about how she decided to be implanted with Essure. ECF No. 22 at 41. However, these details go to causation of the *procedure*, not causation of her *damages*. *See* ECF No. 21 at 14 (Plaintiff "fails to connect [her] symptoms in a particularized way to a particular defect, even via pleading in the alternative."); *McLaughlin v. Bayer Corp*., 172 F. Supp. 3d 804, 836 (E.D. Pa. 2016) ("[T]he Complaint fails to plausibly allege that any particular manufacturing defect actually caused Plaintiffs' injuries and thus fails to allege an essential element of the negligent manufacturing claim.").

Accordingly, for the same reasons stated in the Court's prior Order, these claims are preempted. *See* ECF No. 21 at 12–14. The Court will therefore dismiss these claims.

**VII. Failure-to-Train Claims**

Defendants argue that Plaintiff's failure-to-train claims are expressly and impliedly preempted, that Plaintiff fails to allege that Defendants violated FDA-approved training

requirements, and that there does not exist a parallel state-law requirement to train, as failure-to-train claims in New Mexico only apply to the employer-employee relationship. ECF No. 23 at 10. Plaintiff does not address these arguments in her Response, and any counterarguments are therefore waived. *See generally* ECF No. 27. Plaintiff instead generally alleges that her claims are not preempted as they are parallel state claims, and that her amended claims are adequately pled. *Id.* at 3–7.

Plaintiff also argues that she lacks evidence regarding training, which prevents her from being able to "prove her case." *Id.* at 7–8. However, her burden at this stage is not proving her case, but instead merely presenting allegations containing "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. This argument is therefore inapposite.

Plaintiff has declined even to cite a parallel state-law requirement to train outside the context of employer-employee relationships. *See generally* ECF No. 27. The Court has also failed to find any contrary authority, and finds these claims are likely preempted. ECF No. 5 at 19. In addition, for the same reasons stated in the Court's prior Order, these claims are inadequately pled and must be dismissed. ECF No. 21 at 14–15.

**VIII. Timeliness of Warranty Claims**

Defendants contend that Plaintiff's claims for breach of warranty pursuant to New Mexico law are untimely as the statute of limitations is four years from the date "delivery" occurs. ECF No. 23 at 16–17. Defendants argue under New Mexico law, "delivery" occurred when Plaintiff was originally implanted with the device in 2011. *Id.* Plaintiff does not contest this. *See generally* ECF No. 27.

However, Plaintiff's Amended Complaint states that Plaintiff "did not have knowledge or sufficient notice that the level of risk of injuries from Essure® was higher than she was originally

led to believe, nor did she learn of any potential wrongdoing on the part of the manufacturer, until her healthcare providers advised her" that her chronic pelvic pain was related to the device, which did not occur until 2018. ECF No. 22 at 43. Plaintiff's Amended Complaint thus alleges her suit was timely filed. *Id.*

Indeed, under the "discovery rule" in New Mexico law, "the cause of action accrues when the plaintiff knows or with reasonable diligence should have known of the injury and its cause." *Maestas v. Zager*, 152 P.3d 141, 147 (N.M. 2007). However, this type of statute of limitation tolling originates from personal injury law, not breach of warranty. *See Nowell v. Medtronic, Inc.*, No. 19-2073, 2021 WL 4979300, at *8 (10th Cir. Oct. 27, 2021) (summarizing case law). Although the Tenth Circuit has now applied the "discovery rule" to the products liability realm, "the New Mexico UCC does not include a discovery rule that applies to claims for a breach of implied warranty," and indeed, "New Mexico [law] is clear that a plaintiff's breach of warranty claim accrues upon tender of delivery 'regardless of the aggrieved party's lack of knowledge of the breach.'" *Id.* (citing N.M. Stat. Ann. § 55-2-725(2)).

These claims are therefore untimely and must be dismissed. *See* ECF No. 21 at 15–16.

**IX. Plaintiff's Request for Discovery**

Defendants contend that Plaintiff's strategy is "filing a vague complaint and then using discovery to figure out whether she has a factual basis for it," which is "precisely what the *Twombly/Iqbal* standard aims to foreclose." ECF No. 28 at 8–9. As to causation, Plaintiff argues she "needs more information to be able to plead that the chronic pelvic pain, surgical explanation, and other injuries were the specific result of device migration or misplacement [] as the imaging

that will be discovered will show this evidence."[3] ECF No. 27 at 4–5. Defendants, however, maintain that "Plaintiff does not need the discovery process to obtain her own medical records . . . ." ECF No. 28 at 7–8. The Court agrees, and is somewhat baffled by Plaintiff's assertion otherwise. *See, e.g.*, D.N.M.LR-Civ. 26.3(d) (requiring a plaintiff whose physical condition is at issue to produce *her own* medical records as part of initial disclosures); *Munoz v. St. Mary-Corwin Hosp.*, 221 F.3d 1160, 1169 (10th Cir. 2000) ("When . . . a plaintiff brings an [] action without any factual basis evincing specific misconduct by the defendants and then bases extensive discovery requests upon conclusory allegations in the hope of finding the necessary evidence of misconduct, that plaintiff abuses the judicial process."); *see also Am. Collision & Auto. Ctr., Inc. v. Windsor-Mt. Joy Mut. Ins. Co.*, No. 11-CV-06947, 2012 WL 4490982, at *9 n.48 (E.D. Pa. Sept. 27, 2012) ("While plaintiffs may plead in the alternative and seek mutually exclusive forms of relief, each cause of action must state a claim upon which relief can be granted.").

## X. Request to Amend

Plaintiff requests in her Response that the Court allow her to amend her Complaint a second time. ECF No. 27 at 8. Defendants contend the Court should deny Plaintiff's request to amend for failure to comply with the Local Rules, and for failure to explain how amendment would cure the deficiencies in the current Complaint. ECF No. 28 at 10–12.

Generally, "bare requests for leave to amend do not rise to the status of a motion and do not put the issue before the district court." *Brooks*, 985 F.3d at 1283; *see also Glenn v. First Nat. Bank in Grand Junction*, 868 F.2d 368, 370−71 (10th Cir. 1989). Additionally, in this District, a proposed amended complaint must normally accompany a motion to amend. D.N.M.LR-Civ. 15.1.

[3] Plaintiff also claims that she has not yet received the PMA from Defendants. ECF No. 27 at 8. Defendants note, however, that they have filed the PMA as Document 23-3. ECF No. 28 at 8.

Indeed, the Court reminded Plaintiff of these requirements in its prior Order, before allowing her to amend in spite of her noncompliance, due to the complexity of the law of medical device-related preemption. ECF No. 21 at 18.

Here, Plaintiff has failed to either include a proposed amended complaint, or to detail what such amendment would entail. *See* ECF No. 27. As the Tenth Circuit has noted, crafting a legally sufficient complaint in this area of law is so difficult that it "has been compared to the task of navigating between Scylla and Charybdis." *Caplinger*, 784 F.3d at 1340. However, Plaintiff has already benefitted from two opportunities to attempt to plead an adequate complaint, and she has now essentially admitted that she has nothing more to add. ECF No. 27 at 4–5, 8 ("[F]ormal discovery is needed before Plaintiff Garcia can give a detailed statement of her claims . . . ."). It thus appears that granting such relief would be futile.

The Court will therefore deny Plaintiff's request.

**CONCLUSION**

For the foregoing reasons, Defendants' Motion to Dismiss First Amended Complaint, ECF No. 23, is **GRANTED** and Plaintiff's claims are **DISMISSED WITH PREJUDICE.**

**IT IS SO ORDERED.**

Margaret Strickland

**MARGARET STRICKLAND**
UNITED STATES DISTRICT JUDGE